REMARKS/ARGUMENTS

Claims 1-36 were pending. Upon entry of the above amendments, claims 1-11 and 34-36 will be cancelled and claims 12, 22, 28, 29, 31 will be amended. No new matter has been added.

Applicants want to explicitly bring to the Examiner's attention Applicant's related application bearing U.S. Serial number 09/690,973 (973 application), which depends from the same provisional application, 60/237,442, as the present application. Applicants also enclose a supplemental information disclosure statement identifying the prior art references cited in the 973 application.

Applicant's pending claims recite drug dosage forms that include a compound susceptible to moisture induced degradation, e.g., thyroid hormone, that is treated with a substantially non-volatile, pharmaceutically acceptable oil to substantially waterproof the compound. The drug dosage forms are prepared by compressing the dosage forms under conditions of low compression of up to 5,000 pounds per square inch per one gram of pharmaceutical composition to limit the quantity of moisture available to react with the thyroid hormone.

Claim Rejection – 35 U.S.C. §103(a)

Claims 12-33 have been rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,051,406 to Satoh ("the Satoh patent").

These rejections are respectfully traversed because there is no reason to believe that a person of ordinary skill in the art would have been motivated to modify the teaching of the Satoh patent to achieve Applicant's inventions recited in claims 12-33, as amended. For

example, there is no evidence suggesting that those of ordinary skill would have been motivated to modify the drug dosage form preparation technique described in the Satoh patent, i.e., *dissolving* an active ingredient in a solvent with albumin, to achieve methods of substantially water proofing a compound by dispersing it in a *pharmaceutically acceptable oil* as described in the pending claims. Moreover, the Satoh patent simply does not teach methods of compacting solid dosage forms at up to 5000 pounds per square inch per gram.

Although the Office Action asserts that it would have been obvious for those of ordinary skill to *disperse* a compound susceptible to moisture induced degradation in oil instead of *dissolving* it in a solvent to substantially water proof the compound, the mere possibility for modification of the Satoh reference falls far short of demonstrating that the requisite modification would have been one those of ordinary skill would have been motivated to make. See MPEP § 2143.01. According to the Satoh patent, an active agent must be dissolved in a solvent, e.g., aqueous solvents, organic solvents, or fatty oils (Col.4, line 64 to Col. 5, line 35), however it does not logically follow that the active agent is waterproofed by placing a compound into solution, or by adding oil to a solution containing an active agent. In contrast to the Satoh patent, the pending claims as amended recite waterproofing a compound susceptible to moisture induced degradation by *dispersing it in oil prior to compaction.*

To the extent the Office Action relies upon the text at col. 4, lines 23-31 for its alleged teaching that compounds susceptible to moisture induced degradation can be waterproofed by dispersion in a pharmaceutically acceptable oil, it is noteworthy that the Office Action does not explain how or why those of ordinary skill who did not have the benefit of Applicant's disclosure would have abandoned the Satoh patent's teaching of dissolving the active agent.

As described in the Satoh patent, the reason for adding oil to a pharmaceutical composition has nothing to do with water proofing the active agent (i.e. "the addition of the fatty oil ... further increases the already improved drug adsorption of the present composition"). Absent such an explanation, the Satoh reference simply cannot be said to render Applicant's claimed subject matter obvious. See MPEP § 2143.01. *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000).

Further, the basis for obviousness stated in the Office Action mailed February 6, 2003 is that limitations drawn to a first and second pharmaceutically acceptable oil in claims 28-33 are "directed to the amount of oil used". However, Applicants do not recite a limitation for a specific quantity of oil. This argument cannot be a basis for obviousness.

Since there is no suggestion in the prior art of water proofing compounds susceptible to water induced degradation by dispersing it in pharmaceutically acceptable oil, and no teaching of preparing drug dosage forms using compression pressures up to 5000 pounds per square inch per gram, there is no motivation to modify the cited reference in a way that would have produced the methods recited in the pending claims. Accordingly, Applicants request that the rejection of claims 12-33 under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

Applicant believes that the foregoing is a full and complete response to the Office Action of record. Accordingly, an early and favorable reconsideration of the rejections and allowance of all of pending claims 12-33 are respectfully requested.

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